Complete Summary

GUIDELINE TITLE

Breast disease. Guide to prevention, diagnosis, and treatment.

BIBLIOGRAPHIC SOURCE(S)

Brigham and Women's Hospital. Breast disease. Guide to prevention, diagnosis and treatment. Boston (MA): Brigham and Women's Hospital; 2001. 9 p. [13 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Breast disease, including

- Breast cancer
- Benign breast symptoms or disease
- Breast pain (mastalgia)

GUIDELINE CATEGORY

Counseling
Diagnosis
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Preventive Medicine
Radiology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide physicians with clear guidelines for screening as well as clinical pathways for risk counseling, diagnosis, and treatment of symptomatic breast disease
- To distinguish the roles of the primary care physician, Breast Center, and breast surgeon

TARGET POPULATION

- Women 20 years of age and older (universal screening recommendation for clinical breast exam and breast self-exam)
- Women 40 years of age and older (universal screening recommendation for mammography)
- Women with palpable breast masses or mastalgia (diagnostic and treatment recommendations)
- Women at high risk of breast cancer (recommendations for genetic counseling or chemoprevention)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening for breast cancer, including mammography, clinical breast exam, and breast self-exam
2. Additional diagnostic procedures, including ultrasound, image-guided core biopsy, and image-guided aspiration, as needed
3. Referral to breast surgeon or routine follow-up by primary care provider
4. Assessment of risk factors for breast cancer and surveillance of major risk factors, including genetic predisposition and genetic counseling
5. Use of tamoxifen as chemoprevention in women at high risk for breast cancer
6. Symptom management for breast pain, including reassurance/conservative therapy (e.g., supportive bra, elimination of caffeine, ibuprofen, warm packs, vitamin E, vitamin B6); evening primrose oil; diuretics; danazol, or bromocriptine
7. Tracking of abnormal mammography results

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality due to breast cancer
- Risk of breast cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches using Medline.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guideline recommendations were reviewed by Patricia R. Kennedy, MD, Medical Director, Faulkner Breast Centre at Faulkner Hospital and the Women's Health Guidelines Editorial Review Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations For Screening

Mammography

It is well established that annual mammography reduces breast cancer mortality by about 30% in women age 50 to 69. The effects of screening in women age 40 to 49 have been a source of controversy, with legitimate arguments on both sides. On the one hand, data indicates that over a 10-year period, the cumulative risk of a false positive mammogram is about 50%, and the rate of benign biopsy approaches 20%. Moreover, several trials have shown no reduction in mortality from breast cancer in women routinely screened in this age group. On the other hand, two recent large trials have shown reductions in mortality from breast cancer in women under age 50, although these reductions did not reach statistical significance. Several organizations, including the American Medical Association, the American Cancer Society, the National Cancer Society, and the American College of Radiology now recommend annual mammograms for women beginning at age 40, while the American College of Physicians, the United States Preventive Services Task Force and the Canadian Preventive Services Task Force do not. Brigham and Women´s and Faulkner Hospitals support the recommendation of annual screening mammograms for women in this age group.

Clinical Breast Exam

A clinical breast exam (CBE) should be performed annually in all women 20 and older. It should include inspection of the nipple for recent inversion or excoriation and examination of the skin for erythema and retraction. To check for retraction, the patient is asked to place her hands on her waist and contract her pectoralis muscles, then to bring her arms over her head. Palpation should begin with the periclavicular and axillary nodes and should progress to a systematic examination of the entire breast, including tissue overlying the sternum, the inframammary fold and the retroareolar area.

Breast Self-Exam

Optimally, breast self-exam (BSE) is performed 5 to 7 days after the onset of menstruation, when the breast tissue is least engorged in premenopausal women and on the same day of the month for postmenopausal women. Randomized controlled clinical trials have shown no reduction in mortality from breast cancer among women who performed monthly BSE. However, since BSE is inexpensive

and noninvasive, most physicians recommend it as a screening method to their patients. Patients who find BSE to be anxiety-provoking can be reassured that annual clinical breast examination and screening mammography are sufficient for breast cancer screening.

Risk Determination

Although a few lifestyle factors have been associated with an increased risk of breast cancer, the strongest risk factors are non-modifiable. Therefore, it behooves the primary care physician (PCP) to identify the women at high risk who might benefit from genetic counseling or chemoprevention.

Major Risk Factors

- Genetic Predisposition
    - Family history of breast or ovarian cancer. BRCA1/2 mutation: family history of early onset breast cancer, often in more than one relative; may include ovarian cancer; or known mutation in patient or close relative.
    - Li Fraumeni Syndrome (p53): Family history of early onset breast cancer plus sarcoma, adrenal carcinoma, childhood cancers, or other cancers before age 45.
    - Family history, not genetically defined: Multiple close relatives in one lineage with breast cancer, particularly if premenopausal at diagnosis.
- Histologic risk factors. Previous breast cancer or ductal carcinoma in situ. Previous biopsy indicating lobular carcinoma in situ, atypical ductal hyperplasia, or atypical lobular hyperplasia.
- Therapeutic radiation including breast tissue in the field. Breast cancer risk usually increases 10-15 years after radiation completed.
- Age. Breast cancer incidence increases with age.

Weaker Risk Factors

- Reproductive history. Menarche before age 12, menopause after age 55, nulliparity, first live birth after 30.
- Alcohol consumption. Some observational studies suggest that risk increases with one drink a day and continues to rise linearly with amount of alcohol consumed.
- Postmenopausal hormone use. Majority of published data suggest an association between hormone replacement therapy (HRT) use and breast cancer. The Nurses' Health Study showed a relative risk (RR) of 1.3 to 1.4 in current users; risk increased with age and length of use (relative risk 1.45 with >5 years use). Progestin use may have additive effect on risk.
- Weight. Observational studies suggest that postmenopausal overweight women who are not on hormone replacement therapy may be at increased risk for breast cancer.

Recommendations for surveillance should be made on major risk factors exclusively.

Risk Assessment

Breast cancer risk for postmenopausal women may be assessed using a tool adapted from the Gail model, which is available through the National Cancer Institute. After completing a brief questionnaire, a woman will receive an estimate of her chances of being diagnosed with breast cancer within the next five years. A score of 1.67 or higher indicates that she may benefit from tamoxifen prophylaxis. However, the potential disadvantages (an increased risk of endometrial cancer, vascular events, and menopausal symptoms) should be weighed against the advantages of tamoxifen use.

Genetic Testing for Breast Cancer

Up to 10% of breast cancers are inherited. Mutations in two genes, BRCA1 and BRCA2, appear to be linked to about 50% of inherited breast cancers. Any of several hundred known mutations in either gene confers a 50-85% chance of developing the disease by age 75. The prevalence of BRCA mutations is 2.5% among Ashkenazi Jews and 0.1% in the general population.

DNA testing is available for both genes. Because three distinct mutations are prevalent in Ashkenazi families, the charge - about $350 - is substantially lower than the $2,700 for testing the complete mutation panel in the general population.

There is evidence that prophylactic mastectomy in women with a family history of breast cancer can reduce the risk of breast cancer by 90%. Although tamoxifen prophylaxis is associated with a reduction in risk among women at increased risk by the Gail model, the benefits appear to be limited to estrogen receptor-positive (ER+) tumors. There is some evidence of the effectiveness of prophylactic oophorectomy and tamoxifen prophylaxis in women with mutations, but concern about estrogen receptor-negative (ER-) breast cancers persists. These data are rapidly evolving and should be watched carefully.

Women with a family history who are considering prophylaxis should be informed about the tests and, if they desire, referred to a genetic counselor. The tests may be covered by health insurance. Although there was initial concern that a positive test result would affect a woman's ability to obtain health or life insurance, there have been no known cases of such discrimination to date. Massachusetts enacted a genetic privacy law in 2000.

Management Recommendations for Mastalgia

History and Physical

Consider other sources of chest pain or chest wall pain including pectoralis strain, cervical radiculopathy, costochondritis, hiatal hernia and cholelithiasis.

Reassurance/Conservative Therapy (Effective in Majority of Cases)

- Supportive bra
- Eliminate caffeine
- Ibuprofen: up to 800 mg orally three times per day (po tid)
- Warm packs

- Some evidence of efficacy of vitamin E (400 IU four times per day [qid]) and vitamin B6 (10-20 mg four times per day), but neither have been evaluated in large clinical trials

For Continued or Severe Symptoms

- There is some evidence for the effectiveness of evening primrose oil, but no data from large trials. Typically, it is administered in a 3 gram daily dose for 12 months, and requires 4 months of use before response is appreciated by patients. A minority have side effects—primarily nausea/bloating. In about half of patients, symptoms recur, but are less severe.
- If breast pain is cyclical and recurrent (particularly premenstrually) a diuretic may be helpful.
- Some reports indicate that danazol and bromocriptine are effective for breast pain, but these therapies are not commonly used at Brigham and Women´s and Faulkner Hospitals.

For Tracking Abnormal Mammography Results

At Brigham and Women's and Faulkner Hospitals, patients are informed of the results of their mammogram by the radiologist on the day of their appointment. If further testing is necessary, the primary care physician (or ordering physician) is informed by the radiologist of the need for short interval follow-up, biopsy, or consultation with a breast surgeon. The primary care physician or ordering physician is responsible for ensuring that the recommended testing or follow-up is carried out. Physicians should have a tracking system to ensure that patients follow up appropriately and that results are communicated to patients in a timely manner.

CLINICAL ALGORITHM(S)

The original guideline document contains clinical algorithms for:

- Results of Screening Mammogram
- Nipple Discharge
- Palpable Mass
- Breast Pain

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Guideline recommendations are based on a comprehensive assessment of the recent literature on breast cancer and the Controlled Risk Insurance Company (CRICO) Breast Care Management Algorithm.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- There is increasing evidence that mammographic screening alone can reduce the breast-cancer death rate by 30%, primarily through the identification of smaller, node negative invasive breast cancers. Studies have shown that compliance with screening is significantly increased by in-person and telephone counseling, especially in minority populations. Advances in biopsy techniques, surgery, chemotherapy, hormonal treatment, and supportive therapy have substantially reduced morbidity. The identification of high-risk women and the use of tamoxifen for chemoprevention and prophylaxis have demonstrated potential in preventing the disease in the most vulnerable population.
- The primary care physician can play an important role in further reducing the morbidity and mortality associated with the disease by encouraging women to undergo screening and by referring women who have findings suggestive of breast cancer to the appropriate channels for diagnosis and treatment.

Subgroups Most Likely to Benefit:

African American women, since epidemiologic data indicate that African American women have higher mortality from breast cancer than white women

POTENTIAL HARMS

- Evening primrose oil for mastalgia: A minority of patients have side effects—primarily nausea/bloating.
- Tamoxifen prophylaxis has potential disadvantages, including increased risk of endometrial cancer, vascular events, and menopausal symptoms.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to convey rigid standards, but instead should be tailored to the needs of the individual woman.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Brigham and Women's Hospital. Breast disease. Guide to prevention, diagnosis and treatment. Boston (MA): Brigham and Women's Hospital; 2001. 9 p. [13 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001

GUIDELINE DEVELOPER(S)

Brigham and Women's Hospital (Boston) - Hospital/Medical Center

SOURCE(S) OF FUNDING

Funding was provided by Brigham and Women's Hospital.

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Breast Care Guideline Authors: Carolyn M. Kaelin, MD, FACS; Darrell N. Smith, MD; Judy E. Garber, MD; Roger Christian, MD; Esther Rhei, MD; Linda S. Jaffe, MD; Soheyla D. Gharib, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Brigham and Women's Hospital Web site.

Print copies: Available from the Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; telephone: (800) BWH-9999; Web site: www.brighamandwomens.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 28, 2003. The information was verified by the guideline developer on February 10, 2003.

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